



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP - 9 1998

Food and Drug Administration
Washington, DC 20204

John B. McCandless
Vice President and Chief Operating Officer
USANA, Inc.
3838 West Parkway Boulevard
Salt Lake City, Utah 84120-6336

6100 '98 SEP 11 P1:54

Dear Mr. McCandless:

This is in response to your letter of September 4, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that USANA, Inc. is making the following claim, among others, for the product "Poly C:"

"...adults who took supplement vitamin C had a significantly lower death rate from heart attack and stroke..."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to mitigate, treat, cure, or prevent disease, namely heart attack and stroke. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Denver District Office, Office of Compliance, HFR-SW240

975-0163

LE 9218

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f, OSN#61056)

HFD-310 (BWilliams)

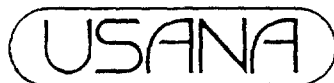
HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

f/t:HFS-456:rjm:9/9/98:docname:61056.adv:disc31



6/05/98

September 4, 1998

Express Mail Label No. EI820826361 US



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. S.W.
Washington D.C. 20204

RE: *Notification of marketing a dietary supplement that bears on its label or its labeling a statement provided for in section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act.*

Dear FDA Consumer Safety Officer:

USANA, Inc. submits this notification for its dietary supplement products that bear statements of nutritional support in accordance with section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

Manufacturer of Dietary Supplement: USANA, Inc.
3838 West Parkway Blvd.
Salt Lake City, Utah 84120-6336

**Name of Dietary Supplements:
(including brand name)** "Chelated Mineral", "Mega Antioxidant",
"CoQuinone", "Proflavanol", "Poly C",
"CalMag Plus", "Melatonin KL",
"Procosamine", "OptOmega",
"Kid's Choo-ables", "LEAN Formula."

Text of Statements Being Made for "Chelated Mineral":

"Chromium acts to maintain healthy sugar metabolism which is critical to achieve proper blood levels of glucose."

also see decklet 975-C163

“Alpha lipoic acid, also known as thiocytic acid, is a vitamin-like antioxidant that is easily absorbed through the gut and transported across cell membranes, offering protection against a wide variety of free radicals both inside and outside the cell.”

“Once inside the body’s tissues, alpha lipoic acid can be converted to dihydrolipoic acid (DHLA), an equally potent free radical scavenger.”

“The alpha lipoic acid and DHLA can act as metal chelators, binding up excess copper, iron, mercury, and cadmium, thus limiting the negative impacts of these heavy metals on the body.”

Text of Statements Being Made for “Proflavanol”:

“Free radicals have become a devastating enemy to our health. Antioxidants are the weapons that provide the electrons which neutralize these free radicals.”

“Proanthocyanidins (flavanols) appear to be some of the most powerful free-radical scavengers yet discovered.”

“Proanthocyanidins are completely safe, and they are one of the few antioxidants that cross the blood-brain barrier to protect neural tissue.”

“Not only do they neutralize free radicals themselves, but they also conserve and regenerate vitamins C and E. Vitamin E is a powerful free-radical scavenger and flavanols and vitamin C regenerate vitamin E so that it may continue its protective role.”

“Scientifically observed documented benefits of the use of proanthocyanidins include . . . enhanced capillary strength and vascular function.”

“Scientifically observed documented benefits of the use of proanthocyanidins include . . . Enhanced immune resistance.”

“Scientifically observed documented benefits of the use of proanthocyanidins include . . . Increased peripheral circulation, improving vision.”

“Scientifically observed documented benefits of the use of proanthocyanidins include . . . Reduction in premature skin aging and loss of elasticity.”

Text of Statements Being Made for “Poly C”:

“Vitamin C helps to combat free radicals and is important in the synthesis of collagen.”

“ A recent study has found that adults who took supplemental vitamin C had a significantly lower death rate from heart attack and stroke compared to those who didn't take supplemental vitamin C.”

Text of Statements Being Made for “CalMag Plus”:

“CalMag Plus was carefully formulated to enable the following ingredients (calcium, magnesium, boron, silicon, vitamin D) to give you strong and healthy bones.”

“Calcium is also critical to nerve conduction, contraction of muscles, blood clotting, neural function, cell division and electrical conduction in the heart.”

“Calcium helps to regulate blood pressure and is essential for the production and action of enzymes and hormones that regulate digestion, energy, and fat metabolism.”

“Calcium is acquired only through diet and must be provided in adequate amount to improve bone density.”

“CalMag Plus contains high amounts of calcium citrate, accompanied by necessary trace minerals and vitamin D to optimize bone mineralization.”

“Along with Calcium, Magnesium is an important component of strong, healthy bones.”

“Magnesium is involved in the metabolism of carbohydrates and amino acids.”

“Magnesium also plays an important role in neuromuscular contractions and helps regulate the alkaline balance in the body.”

“Magnesium is an activator of hundreds of enzymes which are essential to life.”

“This all-important mineral (magnesium) aids in the mobilization of the ATP enzyme system, which is essential for much of the energy used by the body.”

“New research shows that magnesium is also helpful in neutralizing free radicals.”

“Boron has been shown to reduce calcium excretion and deposition of calcium in the bone.”

“Silicon, present in the connective tissues of the body, is essential for proper calcium utilization. This is key to the calcium mineralization of the bone.”

“Vitamin D must be present to enhance the absorption of calcium in the small intestine and for the utilization of calcium in bone formation. It regulates calcium levels in the blood, which allows calcium to perform its various tasks.”

John B. McCandless declares:

1. That he is Vice President and Chief Operating Officer of Usana, Inc.
(hereinafter "applicant") and is authorized to make this declaration;
2. That information contained in this statement is complete and accurate, and
that USANA, Inc. has substantiation that the statement is truthful and not misleading.

DATED this 4th day of September, 1998.

USANA, INC.

By: JB McCandless
John B. McCandless
Vice President and Chief Operating Officer